

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)


Applicant's or agent's file reference NONE	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US98/21604	International filing date (day/month/year) 09 OCTOBER 1998	Priority date (day/month/year) 10 OCTOBER 1997
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant NVID INTERNATIONAL, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 26 MARCH 1999	Date of completion of this report 22 MARCH 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOHN PAK  Telephone No. 308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/21604

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed☒ the description:

pages 1-22, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the claims:

pages 23-28, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the drawings:

pages 1-8, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the sequence listing part of the description:

pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig. NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/21604

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. . .

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/21604

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	<u>9, 11-20, 26-29</u>	YES
	Claims	<u>1-8, 10, 21-25, 30-35</u>	NO
Inventive Step (IS)	Claims	<u>26-29</u>	YES
	Claims	<u>1-25 and 30-35</u>	NO
Industrial Applicability (IA)	Claims	<u>1-35</u>	YES
	Claims	<u>NONE</u>	NO

2. citations and explanations (Rule 70.7)

Claims 9, 11-20 and 26-29 meet the criteria set forth in PCT Article 33(2) because no single prior art can be found that expressly discloses (i) silver citrate formed from 0.05-0.1 % by volume silver electrolytically generated in a solution of 5-10 % by volume citric acid, (ii) silver citrate from electrolytically generated silver with alcohol and optionally anionic detergent, and (iii) method of making a disinfectant by applying a potential difference to a positive silver electrode and a negative electrode to generate a flow of silver ions in 5-10 % by volume of citric acid in water.

Claims 26-29 meets the criteria set forth in PCT Article 33(3) because the prior art does not disclose or suggest the process of making an aqueous disinfectant by electrolytically generating silver ions in 5-10 percent by volume aqueous citric acid solution, as claimed.

Claims 1-35 meet the criteria set forth in PCT Article 33(4) because the claimed invention finds industrial applicability in the disinfection of various substrates.

Claims 1-8, 10 and 30 lack novelty under PCT Article 33(2) as being anticipated by Srivastava et al.

Srivastava et al. expressly disclose 0.5 % silver citrate aqueous solution. The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. See page 209 and Tables 1 and 3 at pages 211-212. While Srivastava's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. Therefore, instant claims are deemed anticipated.

Claims 1-8 and 10 lack novelty under PCT Article 33(2) as being anticipated by Tsimbler et al. (Chemical Abstracts 87:74283n).

(Continued on Supplemental Sheet.)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 4, 5, 24, 25, 26, 34 and 35 are objected to under PCT Article 6 as being indefinite.

(1) All of the above noted claims recite citric acid as $C_6H_8O_7 \cdot H_2O$. However, this formula is not necessarily and strictly limited to citric acid. It could be another compound that has the same formula. If a formula is to be used, it must be more specific with respect to bond linkage, etc. to ensure that the correct compound is represented.

(2) Claims 4, 24 and 34 recites $(Ag(CA))_x$, but the value for the subscript x is not defined.

(3) Claim 26 recites "creating a solution ..." (emphasis added). The emphasized term makes the claim indefinite as "creating" a solution is different from, for example, "providing." Amendment of said term to "providing" or other acceptable alternative terms is suggested.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A01N 37/04, 55/02, 59/00; A61K 31/19, 31/28, 33/38 and US Cl.: 424/618, 619; 422/22, 28; 514/495, 574, 724

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1.

Group I, claims 1-10, 21-25 and 30-35, drawn to an aqueous disinfectant comprising silver citrate in a solution of citric acid and water and a process of making said disinfectant by using as the silver source electrolytically generated silver.

Group II, claims 11-20, drawn to an aqueous disinfectant comprising silver citrate in a solution of citric acid, water and alcohol such as ethyl alcohol.

Group III, claims 26-29, drawn to a process of making an aqueous disinfectant by (i) providing a solution of 5-10% citric acid in water, (ii) spacing a positive silver electrode relative to a negative electrode for enabling the solution to be located therebetween, and (iii) applying a potential difference to the electrodes to establish a flow of silver ions between the electrodes for silver ions to react with the citric acid to form silver citrate.

The inventions listed as Groups I, II and III do not relate to a single inventive concept under PCT Article 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I and Group II are directed to distinct inventive compositions. It is unclear *a priori* whether the alcohol component in Group II would provide for a materially different complex of silver-citrate-alcohol. Therefore, it is not known at this time whether the composition of Group II is a composition with just one more ingredient than Group I or a materially distinct complex of three components. Thus it cannot be said that a special technical feature is shared by Group I and Group II when the alcohol component may materially alter the complex formed in Group II due to, for example, the availability of another ligand and/or different solubility effect brought on by the alcohol. Special technical feature cannot be found when the ingredients of Group II produce a complex that may be materially distinct from that expected of Group I.

The process of Group III does not share a special technical feature with the process of Group I because the process of Group I is only nominally directed to electrolytic generation of silver, whereas the process of Group III is specific with respect to the spacing of the electrodes, the position of the solution, and result of application of potential difference.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

Chemical Abstracts 87:74283n expressly disclose silver citrate complex in aqueous solution. The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. While the disclosed composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. Therefore, instant claims are deemed anticipated.

Claims 21-25 and 30-35 lack novelty under PCT Article 33(2) as being anticipated by Yamamoto (Chemical Abstracts 118:156836t).

Chemical Abstracts 118:156836t expressly discloses electrolyzing in an aqueous solution containing citrates (and by necessity citric acid) with a silver cathode at 1.5V (preferably $\geq 3V$). The process of the claims 21-25 and 30-35 are directly readable on the process disclosed by Chemical Abstracts 118:156836t. Chelation and formation of a complex are presumed to take place with the same ionic species in the absence of contrary evidence. The claims are thereby anticipated.

Claims 21-25 and 30-35 lack an inventive step under PCT Article 33(3) as being obvious over Yamamoto (Chemical Abstracts 118:156836t).

Chemical Abstracts 118:156836t expressly discloses electrolyzing in an aqueous solution containing citrates (and by

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 11

Continuation of: Boxes I - VIII

necessity citric acid) with a silver cathode at 1.5V (preferably $\geq 3V$). The process of the claims 21-25 and 30-35 are directly readable on the process disclosed by Chemical Abstracts 118:156836t. Chelation and formation of a complex are presumed to take place with the same ionic species in the absence of contrary evidence. The claims therefore lack an inventive step.

Claims 1-20 and 30 lack an inventive step under PCT Article 33(3) as being obvious over Srivastava et al.

Srivastava et al. expressly disclose 0.5% silver citrate aqueous solution as having "very good antibacterial activity against organisms studied (Table 1)" (see p. 213, column 1, second full paragraph). The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. See page 209 and Tables 1 and 3 at pages 211-212. While Srivastava's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. To further add to the antimicrobially active silver citrate another active substance such as alcohol for its own antimicrobial, disinfecting or solvent functionality would have been well within the skill of the routineer in the art. Therefore, the claimed invention as a whole would have been obvious to the routineer in this art; and the instant claims lack unity of invention under PCT Article 33(3).

Claims 1-20 and 30 lack an inventive step under PCT Article 33(3) as being obvious over Maurer et al. (US 4,055,655).

Maurer et al. disclose controlling microbes with a metal complex of heavy metal ion such as silver with a polyfunctional organic ligand such as α -hydroxy polycarboxylic acid (see e.g. claims 1-3 and 8). Citrates are disclosed (column 4, lines 1-13). The aqueous solution (see e.g. column 13, lines 36-39) must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. While Maurer's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. To further add to the antimicrobially active silver citrate another active substance such as alcohol for its own antimicrobial, disinfecting or solvent functionality would have been well within the skill of the routineer in the art. Therefore, the claimed invention as a whole would have been obvious to the routineer in this art; and the instant claims lack unity of invention under PCT Article 33(3).

----- NEW CITATIONS -----

Chem. abstr., Vol. 118, No. 16, 19 April 1993 (Columbus, OH, USA), page 628, column 2, the abstract No. 118:156836t, YAMAMOTO, M. 'Electrochemical removal of discoloration on silver product surface.' JP 04-297599 A, 21 October 1992.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A01N 37/04, 55/02, 59/00; A61K 31/19, 31/28, 33/38 and US Cl.: 424/618, 619; 422/22, 28; 514/495, 574, 724

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1.

Group I, claims 1-10, 21-25 and 30-35, drawn to an aqueous disinfectant comprising silver citrate in a solution of citric acid and water and a process of making said disinfectant by using as the silver source electrolytically generated silver.

Group II, claims 11-20, drawn to an aqueous disinfectant comprising silver citrate in a solution of citric acid, water and alcohol such as ethyl alcohol.

Group III, claims 26-29, drawn to a process of making an aqueous disinfectant by (i) providing a solution of 5-10% citric acid in water, (ii) spacing a positive silver electrode relative to a negative electrode for enabling the solution to be located therebetween, and (iii) applying a potential difference to the electrodes to establish a flow of silver ions between the electrodes for silver ions to react with the citric acid to form silver citrate.

The inventions listed as Groups I, II and III do not relate to a single inventive concept under PCT Article 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I and Group II are directed to distinct inventive compositions. It is unclear *a priori* whether the alcohol component in Group II would provide for a materially different complex of silver-citrate-alcohol. Therefore, it is not known at this time whether the composition of Group II is a composition with just one more ingredient than Group I or a materially distinct complex of three components. Thus it cannot be said that a special technical feature is shared by Group I and Group II when the alcohol component may materially alter the complex formed in Group II due to, for example, the availability of another ligand and/or different solubility effect brought on by the alcohol. Special technical feature cannot be found when the ingredients of Group II produce a complex that may be materially distinct from that expected of Group I.

The process of Group III does not share a special technical feature with the process of Group I because the process of Group I is only nominally directed to electrolytic generation of silver, whereas the process of Group III is specific with respect to the spacing of the electrodes, the position of the solution, and result of application of potential difference.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

Chemical Abstracts 87:74283n expressly disclose silver citrate complex in aqueous solution. The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. While the disclosed composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. Therefore, instant claims are deemed anticipated.

Claims 21-25 and 30-35 lack novelty under PCT Article 33(2) as being anticipated by Yamamoto (Chemical Abstracts 118:156836t).

Chemical Abstracts 118:156836t expressly discloses electrolyzing in an aqueous solution containing citrates (and by necessity citric acid) with a silver cathode at 1.5V (preferably $\geq 3V$). The process of the claims 21-25 and 30-35 are directly readable on the process disclosed by Chemical Abstracts 118:156836t. Chelation and formation of a complex are presumed to take place with the same ionic species in the absence of contrary evidence. The claims are thereby anticipated.

Claims 21-25 and 30-35 lack an inventive step under PCT Article 33(3) as being obvious over Yamamoto (Chemical Abstracts 118:156836t).

Chemical Abstracts 118:156836t expressly discloses electrolyzing in an aqueous solution containing citrates (and by

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 11

necessity citric acid) with a silver cathode at 1.5V (preferably $\geq 3V$). The process of the claims 21-25 and 30-35 are directly readable on the process disclosed by Chemical Abstracts 118:156836t. Chelation and formation of a complex are presumed to take place with the same ionic species in the absence of contrary evidence. The claims therefore lack an inventive step.

Claims 1-20 and 30 lack an inventive step under PCT Article 33(3) as being obvious over Srivastava et al.

Srivastava et al. expressly disclose 0.5% silver citrate aqueous solution as having "very good antibacterial activity against organisms studied (Table 1)" (see p. 213, column 1, second full paragraph). The aqueous solution must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. See page 209 and Tables 1 and 3 at pages 211-212. While Srivastava's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. To further add to the antimicrobially active silver citrate another active substance such as alcohol for its own antimicrobial, disinfecting or solvent functionality would have been well within the skill of the routineer in the art. Therefore, the claimed invention as a whole would have been obvious to the routineer in this art; and the instant claims lack unity of invention under PCT Article 33(3).

Claims 1-20 and 30 lack an inventive step under PCT Article 33(3) as being obvious over Maurer et al. (US 4,055,655).

Maurer et al. disclose controlling microbes with a metal complex of heavy metal ion such as silver with a polyfunctional organic ligand such as alpha-hydroxy polycarboxylic acid (see e.g. claims 1-3 and 8). Citrates are disclosed (column 4, lines 1-13). The aqueous solution (see e.g. column 13, lines 36-39) must necessarily contain certain amounts of citric acid due to equilibrium and disassociation characteristics of ionic species. While Maurer's composition does not expressly contain electrolytically generated silver, chemically generated silver combined with citrate anionic moiety is presumed to combine to produce the same substance, absent evidence to the contrary. To further add to the antimicrobially active silver citrate another active substance such as alcohol for its own antimicrobial, disinfecting or solvent functionality would have been well within the skill of the routineer in the art. Therefore, the claimed invention as a whole would have been obvious to the routineer in this art; and the instant claims lack unity of invention under PCT Article 33(3).

----- NEW CITATIONS -----

Chem. abstr., Vol. 118, No. 16, 19 April 1993 (Columbus, OH, USA), page 628, column 2, the abstract No. 118:156836t.
YAMAMOTO, M. 'Electrochemical removal of discoloration on silver product surface.' JP 04-297599 A, 21 October 1992.